



February 8, 2021

Medrad, Inc.
Mike Burnside
Regulatory Affairs Manager
9055 Evergreen Blvd NW
Minneapolis, Minnesota 55433-8003

Re: K113363

Trade/Device Name: AngioJet Solent Dista Thrombectomy Set
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ, KRA

Dear Mike Burnside:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 06, 2012. Specifically, FDA is updating this SE Letter as an administrative correction because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W.
O'Connell -S

Digitally signed by
Gregory W. O'Connell
-S
Date: 2021.02.08
08:08:00 -05'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

JUN - 6 2012

MEDRAD, Inc.
c/o Mike Burnside
Regulatory Affairs Manager
9055 Evergreen Boulevard NW
Minneapolis, MN 55433-8003

Re: K113363

Trade/Device Name: AngioJet Solent Dista Thrombectomy Set
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE, KRA
Dated: March 28, 2012
Received: April 11, 2012

Dear Mr. Burnside:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. However, we remind you that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Mr. Mike Burnside

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): K113363

Device Name: AngioJet® Solent™ Dista Thrombectomy Set

Indications for Use:

The AngioJet Solent Dista Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apart and remove thrombus from:

- upper and lower extremity peripheral arteries $\geq 1.5\text{mm}$ in diameter and
- for use with the AngioJet Ultra Power Pulse Kit for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)


(Division Sign-Off) of CDRH, Office of Device Evaluation (ODE)
Division of Cardiovascular Devices

510(k) Number: K113363

K113363

JUN - 6 2012

Section 5 – 510(k) Summary

Submitter: MEDRAD, INC.
9055 Evergreen Boulevard NW
Minneapolis, MN 55433-8003 USA

Contact Person: Mike Burnside
Regulatory Affairs Manager
Phone: (763) 717-1077
Fax: (763) 780-2227
Email: micahel.burnside@possis.com

Date Prepared: February 16, 2012

Trade Name: AngioJet® Solent™ Dista Thrombectomy Set

Classification: 870.5150 and 870.1210

Product Code: DXE and KRA

Predicate Device(s): The subject device is equivalent to the following devices:

- K111182 AngioJet Ultra Solent Omni Thrombectomy Set
- K072769 AngioJet Ultra XMI Thrombectomy Set

Device Description: AngioJet Solent Dista Thrombectomy Set is a sterile, single use, disposable set that includes a Thrombectomy Catheter and Pump in one combined unit. The AngioJet Solent Dista Thrombectomy Set is used with the AngioJet Ultra Console.

Intended Use: The AngioJet Solent Dista Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apart and remove thrombus from:

- upper and lower extremity peripheral arteries $\geq 1.5\text{mm}$ in diameter and
- for use with the AngioJet Ultra Power Pulse Kit for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.

Comparison to predicate: Design changes were made to the predicate device which included: change in length of device, changes to the jet body, changes to catheter shaft, changes to distal section of catheter, and changes to diameter of catheter.

Performance Data Bench and laboratory testing was performed to support a determination of substantial equivalence to the predicate device. Results from the testing provide assurance that the proposed device conforms to the requirements for its intended use. This included the following testing:

- Biocompatibility
 - Cytotoxicity (ISO 10993-5)
 - Intracutaneous Reactivity (ISO 10993-10)
 - Sensitization (ISO 10993-10)
 - Acute Systemic Toxicity (ISO 10993-11)
 - Material Mediated Pyrogen (ISO 10993-11)

- Physiochemical (ISO 10993-18)
- Hemocompatibility
 - ASTM Hemolysis (ISO 10993-4)
 - Partial Thromboplastin Time Assay (ASTM F2382-04)
 - C3a Complement Activation (ISO 10993-4)
 - SC5b-9 Complement Activation (ISO 10993-4)
 - Thromboresistance (ISO 10993-4)
- Catheter operational characteristics
- Leak testing
- Corrosion
- Dimensional verification
- Guide wire compatibility tests
- Particulate generation
- Tracking/function in tortuosity
- Extended use
- Clot removal
- Hemolysis
- Thermal dose
- Mechanical integrity (tensile strengths, compression / buckling, torque testing)
- GLP Animal acute and chronic safety studies.

Conclusion:

MEDRAD considers the AngioJet Solent Dista Thrombectomy Set to be substantially equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in functional design, materials, indications for use, and principles of operation. Testing (bench, biocompatibility testing, and animal testing) verified that the new device is substantially equivalent to the predicate devices.